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January 21, 2008

Via EFS

Examiner DANEGA, RENEE A  
Art Number 4111  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: ***Patent Application "Monitoring Apparatus for Ambulatory Subject and a Method for Monitoring the Same"***  
***Serial No. 10/568,511***  
***Filing Date: February 15, 2006***  
***Attorney Docket No. 1491.03***

Dear Examiner Danega:

Regarding the Office Action for the above-identified application, please be informed that the claims were amended in the international stage of the corresponding PCT International Application Number PCT/AU2004/001081. The examination should be based on the amended claims. Please withdraw the currently outstanding office action, and issue a new office action based on the amended claims.

As written on the attached copy of the transmittal letter, a copy of international preliminary report that includes amendment of the claims was submitted when entering the national stage, and the application fee was paid based on the number of independent claims of the amended claims. The amendment was also specified in the inventor's declaration.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any over-payment to Deposit Account No. 16-0310.

Very truly yours,

Park Law Firm

A handwritten signature in black ink, appearing to be "Choongseop Lee", written over a horizontal line.

Choongseop Lee  
USPTO Registration No. 57,051

CSL/cp  
Enc.

Clients\1491.03\CSL2Examiner\_20080121\_Response

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER 1491.03
		U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
INTERNATIONAL APPLICATION NO. PCT/AU2004/001081	INTERNATIONAL FILING DATE 13 AUGUST 2004	PRIORITY DATE CLAIMED 15 AUGUST 2003
TITLE OF INVENTION A MONITORING DEVICE FOR AN AMBULATORY SUBJECT AND A METHOD FOR MONITORING THE SAME		
APPLICANT(S) FOR DO/EO/US MATHIE, MERRYN J. / CELLER, BRANKO G. / LOVELL, NIGEL H.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371. 3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). 		
Items 11 to 20 below concern document(s) or information included: 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information: A Copy of the International Search Report / A Copy of the International Preliminary Report		

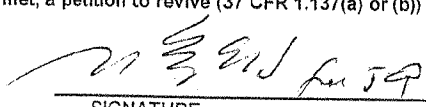
**COPY**

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required by the USPTO to process an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11. Time will be allowed for gathering information, preparing, and submitting the completed form to the USPTO. Time will be allowed for you to complete this form and/or suggestions for reducing this burden, should be sent to the Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

DATE OF DEPOSIT: 02/15/06  
**ED257505253** US.  
 I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS" MAIL POST OFFICE TO ADDRESSEE SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO TO MAIL STOP PCT, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450  
 BY Yoo Jung Lee PRINT Yoo Jung Lee

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO. PCT/AU2004/001081		ATTORNEY'S DOCKET NUMBER 1491.03	
The following fees have been submitted				CALCULATIONS PTO USE ONLY	
21. <input checked="" type="checkbox"/> Basic national fee ..... \$300				\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) .. \$100 All other situations .. \$200				\$ 200.00	
23. <input checked="" type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority .. \$100 International Search Report prepared and provided to the Office .. \$400 All other situations .. \$500				\$ 500.00	
TOTAL OF 21, 22 and 23 = \$1,000.00				\$ 1,000.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	19 - 20 =		x \$ 50	\$	
Independent claims	4 - 3 =	1	x \$200	\$ 200.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
TOTAL OF ABOVE CALCULATIONS =				\$ 1,200.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
SUBTOTAL =				\$ 600.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				+	\$
TOTAL NATIONAL FEE =				\$ 600.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$
TOTAL FEES ENCLOSED =				\$ 600.00	
				Amount to be refunded:	\$
				Amount to be charged:	\$
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>16-0310</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input checked="" type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p>					
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.					
SEND ALL CORRESPONDENCE TO:					
Customer No. 29338			 SIGNATURE PARK, JOHN K. NAME 37,904 REGISTRATION NUMBER		

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**DECLARATION FOR UTILITY OR  
DESIGN  
PATENT APPLICATION  
(37 CFR 1.63)**Declaration  
Submitted  
With Initial  
Filing

OR

Declaration  
Submitted after Initial  
Filing (surcharge  
(37 CFR 1.16 (e))  
required)Attorney Docket  
Number

1491.03

First Named Inventor

Merryn J Mathie

**COMPLETE IF KNOWN**

Application Number

PCT/AU2004/001081

Filing Date

13 August 2004

Art Unit

Examiner Name

I hereby declare that:

Each inventor's residence, mailing address, and citizenship are as stated below next to their name.

I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

A Monitoring Device For An Ambulatory Subject And A Method For Monitoring The Same

(Title of the Invention)

the specification of which



is attached hereto

OR



was filed on (MM/DD/YYYY)

13 August 2004

as United States Application Number or PCT International

Application Number

PCT/AU2004/001081

and was amended on (MM/DD/YYYY)

06/28/2005

(if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
2003904336	Australia	08/15/2003	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
60/514,969	USA	10/27/2003	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

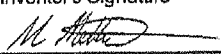
This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1450.

If you need assistance completing the form, call 1-800-PTO-9199 and select option 2.

**COPY**

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**DECLARATION — Utility or Design Patent Application**

Direct all correspondence to: <input type="checkbox"/> The address associated with Customer Number: <input type="text"/>		OR <input checked="" type="checkbox"/> Correspondence address below	
Name Park Law Firm ( a professional corporation)			
Address 3255 Wilshire Boulevard, suite 1110			
City Los Angeles		State California	ZIP 90010
Country United States of America	Telephone 213-389-3777	Email firm@parklaw.com	
<b>WARNING:</b> Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.			
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.			
NAME OF SOLE OR FIRST INVENTOR:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any]) Merryn Joy		Family Name or Surname Mathie	
Inventor's Signature 		Date 8 February 2006	
Residence: City Sydney	State NSW	Country Australia	Citizenship Australian
Mailing Address c/o SAMPARK & CO Suite 415, 375 George Street			
City Sydney	State NSW	Zip 2000	Country Australia
<input checked="" type="checkbox"/> Additional inventors or a legal representative are being named on the <u>1</u> supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.			

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<b>DECLARATION</b>	<b>ADDITIONAL INVENTOR(S)</b> Supplemental Sheet
Page <u>1</u> of <u>1</u>	

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Branko G		Caller	
Inventor's Signature <i>By Caller</i>		8 February 2006 Date	
Sydney Residence: City	NSW State	Australia Country	Australian Citizenship
c/o SAMPARK & CO Suite 415, 375 George Street			
Mailing Address			
Sydney City	NSW State	2000 Zip	Australia Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Nigel H		Lovell	
Inventor's Signature <i>Nigel Lovell</i>		8 February 2006 Date	
Sydney Residence: City	NSW State	Australia Country	Australian Citizenship
c/o SAMPARK & CO Suite 415, 375 George Street			
Mailing Address			
Sydney City	NSW State	2000 Zip	Australia Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 21 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1 (b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 6-16 as originally filed/furnished
  - pages\* 1-5, 5a received by this Authority on 28 June 2005 with the letter of 27 June 2005
  - pages\* received by this Authority on with the letter of
- ☒ the claims:
- pages as originally filed/furnished
  - pages\* as amended (together with any statement) under Article 19
  - pages\* 17-21 received by this Authority on 28 June 2005 with the letter of 27 June 2005
  - pages\* received by this Authority on with the letter of
- ☒ the drawings:
- pages 1/6-6/6 as originally filed/furnished
  - pages\* received by this Authority on with the letter of
  - pages\* received by this Authority on with the letter of
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to the sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to the sequence listing (*specify*):

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**COPY**

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001081

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims 1-19	YES
	Claims	NO
Inventive step (IS)	Claims 1-19	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-19	YES
	Claims	NO

## 2. Citations and explanations (Rule 70.7)

Claims 1-19 meet the criteria under PCT Articles 33(2)-33(4) with regard to novelty, inventive step and industrial applicability.

The notable difference between the invention as defined in claims 1-19 and what is disclosed in any of the cited references is that the processing unit of the monitoring apparatus not only determines the at least one instant ambulatory performance indicia of the subject from at least one determined instant acceleration of the subject in one or more instants of time but it also determines the at least one designated performance threshold from at least one previously determined instant ambulatory performance indicia.

This feature provides the monitoring apparatus with an important adaptive threshold capability that is performed in situ within the processing unit itself and not a threshold that is determined by a clinician or other operator and inputted by specification.

This adaptive threshold capability provides two distinct advantages. Firstly, it caters for calibration or run in periods which do not require manual clinician or user intervention in relation to setting the threshold magnitudes. Secondly, it provides for adaptive cooperative changes to threshold magnitudes and mitigates against false alarms in the case of long term ambulatory performance changes.

The subject matter of claims 1-19 is therefore novel, involves an inventive step and possesses industrial applicability.



## A MONITORING APPARATUS FOR AN AMBULATORY SUBJECT AND A METHOD FOR MONITORING THE SAME

### FIELD OF THE INVENTION

- 5 The invention is in the field of monitoring methods and apparatus for ambulatory subjects.

### PRIOR ART

In accordance with the statistics in some countries the population is ageing and it is projected that by the year 2051 those aged 65 years and over will constitute approximately one quarter of the total population.

10

Falls are one of the greatest risks facing this group and in the over 65 age group, accidents are the fifth highest cause of death, and approximately two thirds of accidents are falls. Falls also account for more than half of all injury-related hospital admissions in this group.

- 15 Falls and collapse are associated with functional decline, leading to disability, dependence and nursing home placement, even in cases where the fall did not cause injury. Up to half of all older people who fall or collapse without suffering injuries are unable to get up without assistance.

- 20 In the case of the elderly or infirm persons living alone, an inability to rise can lead to serious consequences of extreme distress, muscle damage, pneumonia, pressure sores, dehydration, hypothermia and mortality. Many such people become afraid and so restrict their daily activities and exercise, which in turn leads to a further reduction in health and wellbeing.

- 25 Some personal alarm systems provide such venerable people with an emergency button however this technology is rendered ineffective if the person is unable to press the button due to unconsciousness, injury or immobility.

- 30 Furthermore the ageing population and the related increasing prevalence of chronic disease are placing a large burden on the hospital system. There is a need to provide alternatives to hospital care for these patients.

- 35 One of the most important considerations in independent living is functional status; that is, the ability of a person to carry out routine daily tasks in his or her normal (home) environment. There are many different measurements that provide indication of functional status. These include, but are not limited to, the time taken to rise from sitting, postural sway when standing, walking speed, and step rate variability.

Traditionally, these parameters have been measured in a dedicated laboratory in an expensive, time-consuming procedure, or they have been measured subjectively in the clinic or home using clinician observation or patient recall.

It is therefore an object of the invention to overcome some of the problems of the prior art or at least to provide a useful alternative.

#### SUMMARY OF THE INVENTION

- 5 One aspect of a preferred embodiment of the invention provides a monitoring apparatus for an ambulatory subject including:
- a portable monitor mountable on the subject that includes an accelerometer that measures the instant acceleration of the subject in one or more determined directions;
  - a processing unit that:
    - 10 a) determines at least one instant ambulatory performance indicia of the subject from at least one determined instant acceleration of the subject in one or more instants of time;
    - b) determines at least one designated performance threshold from at least one previously determined instant ambulatory performance indicia;
    - c) determines if the subject's instant ambulatory performance indicia is below or above the at least  
15 one designated performance threshold;
    - d) initiates at least one event if the determined instant ambulatory performance indicia is above or below the determined at least one designated performance threshold; and
  - a communications unit that communicates an initiated event to a remote receiver.

- 20 Preferably the at least one designated performance threshold is determined by the processing unit from a plurality of previously determined instant ambulatory performance indicia.

- Preferably the at least one event is initiated only if the determined instant ambulatory performance indicia is below or above the determined at least one designated performance threshold for a designated period  
25 of time.

Preferably the designated first period of time is determined from a plurality of previously determined instant ambulatory performance indicia.

- 30 Preferably the accelerometer simultaneously determines the acceleration of the subject in three orthogonal directions.

- Preferably the portable monitor is configured to be mounted on an upright ambulatory such that one of the three orthogonal directions is in a vertical direction or within a designated angle of the vertical direction.  
35

Preferably an initiated event is communicated by the apparatus to the remote receiver by wireless communication.

In another embodiment it is also preferred:

- a first instant ambulatory performance indicia representative of movement activity in the subject is determined from the instant magnitude of the sum of the instant acceleration of the subject in one or more determined directions;
- a first acceleration threshold magnitude that is representative of a lack of normal expected subject movement is designated as a first designated performance threshold;
- a first event representative of 'an absence of a normal amount of movement in the subject indicative of a possible inability to rise due to a collapse or other adverse event' is initiated if the determined first instant ambulatory performance indicia is below the first designated acceleration threshold magnitude for a first designated period of time.

It is also further preferred:

- a second instant ambulatory performance indicia representative of the instant cranio-caudal angle of the subject relative to an upright disposition of the subject, is determined from at least one of the determined instant acceleration of the subject in one or more determined directions;
- an angle magnitude that is representative of a cranio-caudal angle of the subject relative to an upright subject where the disposition of the subject is deemed to be no longer upright is designated as a second designated performance threshold;
- a second acceleration threshold magnitude representative of an abnormally high subject movement is designated as a third designated performance threshold; and
- a second event representative of an abnormal acceleration of the subject followed by a laying down subject disposition indicative of a possible fall coupled with a subsequent absence of getting up from the laying down disposition indicative of a possible debilitating fall is initiated if:
  - a) the determined first instant ambulatory performance indicia is above the second designated acceleration threshold for a second designated period of time; and
  - b) within a third designated period of time of the end of the second designated period of time the determined second instant ambulatory performance indicia is greater than the designated angle threshold; and then
  - c) the determined first instant ambulatory performance indicia is below the first designated acceleration threshold magnitude for a first designated period of time.

Another aspect of the invention provides a method of monitoring an ambulatory subject including:

- a) mounting a portable monitor on the subject that includes an accelerometer to measure simultaneously the instant acceleration of the subject in at least three different directions at different instants in time;
- b) using a processing unit in communication with the portable monitor to determine a plurality of instant ambulatory performance indicia based on the determined instant acceleration of the subject;

- c) using the processing unit to determine at least one designated performance threshold corresponding to the each ambulatory performance indicia from at least one previously determined corresponding instant ambulatory performance indicia;
- d) using the processing unit to determine if the subject's instant ambulatory performance indicia is below or above the corresponding at least one designated performance threshold and initiating a corresponding event;
- e) using a communications unit to communicate an initiated event to a remote receiver.

Preferably the at least one designated performance threshold is determined from a plurality of previously determined instant performance indicia, and the designated performance threshold responsively and cooperatively adapts to statistical changes in previously determined instant performance indicia over time.

Preferably the event is initiated only if the determined instant ambulatory performance indicia is below or above the determined at least one designated performance threshold for a designated period of time.

Another aspect of the invention provides a method of monitoring an ambulatory subject including:

- a) mounting a portable monitor on the subject that includes an accelerometer to measure the instant acceleration of the subject in one or more determined directions;
- b) using a processing unit in communication with the portable monitor to determine at least one instant ambulatory performance indicia of the subject from at least one determined instant acceleration of the subject in one or more instants of time;
- c) using the processing unit to determine at least one designated performance threshold from at least one previously determined instant ambulatory performance indicia;
- d) using the processing unit to determine if the subject's instant ambulatory performance indicia is below or above the at least one designated performance threshold and initiating a corresponding event;
- e) using the processing unit to initiate at least one event if the determined instant ambulatory performance indicia is above or below the determined at least one designated performance threshold; and
- f) using a communications unit to communicate an initiated event to a remote receiver.

Preferably the at least one designated performance threshold is determined by the processing unit from a plurality of previously determined instant performance indicia.

Preferably the designated performance threshold responsively and cooperatively adapts to statistical changes in previously determined instant performance indicia over time.

Another aspect of the invention provides a monitoring apparatus for an ambulatory subject including:

- a portable monitor mountable on the subject that includes an accelerometer that simultaneously measures the instant acceleration of the subject in at least three different directions;
- a processing unit that:
  - a) is in communication with the portable monitor;
  - 5      b) determines the instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions;
  - c) determines if the determined instant magnitude does not exceed a first designated acceleration threshold magnitude for a first designated period of time, where the first designated acceleration threshold magnitude is representative of a lack of normal expected subject movement;
  - 10      d) initiates an event representative of an absence of a normal amount of movement in the subject indicative of a possible inability to rise due to a collapse or other adverse event if the determined instant magnitude does not exceed the first designated acceleration threshold magnitude for at least the first designated period of time;
  - 15      e) determines the first designated acceleration threshold magnitude from a plurality of previously determined instant magnitudes; and
- a communications unit that communicates an initiated event to a remote receiver.

In this aspect of the invention it is preferred:

- 20      ▪ the processing unit:
  - a) determines if the determined instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions exceeds a second designated acceleration threshold magnitude for at least a second designated period of time;
  - b) determines the second designated acceleration threshold magnitude from a plurality of previously determined instant magnitudes;
  - 25      c) determines the magnitude of the instant angle of the subject being the magnitude of the angle between the cranio-caudal axis of the subject and the cranio-caudal axis of the subject when in an upright disposition from at least one of the determined instant acceleration of the subject in one or more determined directions;
  - 30      d) determines if the determined instant angle of the monitor is greater or less than a designated angle magnitude threshold; and
  - e) initiates an event representative of an abnormally high acceleration of the subject followed by a laying down subject disposition indicative of a possible fall coupled with a subsequent absence of getting up from the laying down disposition indicative of a possible debilitating fall if:
    - 35      i. the determined instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions exceeds the second designated acceleration threshold magnitude for at least a second designated period of time; and

- II. within a third designated period of time after the end of the second designated period of time the determined instant angle of the subject is greater than the designated angle magnitude threshold; and
- 5 III. within the third designated period of time after the end second designated period of time the instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions does not exceed a third designated acceleration magnitude for at least a fourth designated period of time.

10 Preferably the accelerometer simultaneously determines the acceleration of the subject in three orthogonal directions.

Preferably the portable monitor is mounted on an upright subject in an orientation so that one of the three orthogonal directions is in a vertical direction or within a designated angle of the vertical direction.

- 15 In another aspect the invention provides a method for detecting a person's inability to rise after a fall, collapse or other adverse event using a triaxial accelerometer included in a personal wearable ambulatory monitoring device. The first part of the procedure involves the detection of an inability to rise caused by a fall event. The first step in the method is sampling an output from the triaxial accelerometer that is indicative of body acceleration and body angle. The next step is to determine whether a fall has
- 20 taken place by comparing the magnitude of the acceleration vector to an acceleration magnitude threshold for a period equal to a time duration threshold to determine the presence of an abnormal acceleration. If an abnormal acceleration is detected then the body angle is compared to a threshold value to identify a body state indicative of lying. A subsequent absence of movement is detected by comparing the magnitude of the acceleration vector to a second acceleration magnitude threshold.
- 25 The second part of the procedure involves the detection of an inability to rise due to collapse or other adverse event. The first step in the method is sampling an output from the triaxial accelerometer that is indicative of body acceleration and body angle. The next step is to identify an inability to rise by comparing the magnitude of the acceleration vector to an acceleration magnitude threshold for a period equal to a time duration threshold to determine the absence of a normal amount of movement.

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In another aspect of the invention it provides a method for monitoring a person's movement to detect an inability to rise due to a fall through using a triaxial accelerometer included in a personal monitoring system that consists of a receiver unit and a personal monitoring device, which communicates with the

## CLAIMS

1. A monitoring apparatus for an ambulatory subject including:
  - a portable monitor mountable on the subject that includes an accelerometer that measures the instant acceleration of the subject in one or more determined directions;
  - 5   ▪ a processing unit that:
    - a) determines at least one instant ambulatory performance indicia of the subject from at least one determined instant acceleration of the subject in one or more instants of time;
    - b) determines at least one designated performance threshold from at least one previously determined instant ambulatory performance indicia;
    - 10   c) determines if the subject's instant ambulatory performance indicia is below or above the at least one designated performance threshold;
    - d) initiates at least one event if the determined instant ambulatory performance indicia is above or below the determined at least one designated performance threshold; and
    - a communications unit that communicates an initiated event to a remote receiver.
- 15   2. A monitoring apparatus in accordance with claim 1 wherein the at least one designated performance threshold is determined by the processing unit from a plurality of previously determined instant ambulatory performance indicia.
- 20   3. A monitoring apparatus in accordance with claim 1 wherein the at least one event is initiated only if the determined instant ambulatory performance indicia is below or above the determined at least one designated performance threshold for a designated period of time.
- 25   4. A monitoring apparatus in accordance with claim 3 wherein the designated first period of time is determined from a plurality of previously determined instant ambulatory performance indicia.
5. A monitoring apparatus in accordance with claim 1 wherein the accelerometer simultaneously determines the acceleration of the subject in three orthogonal directions.
- 30   6. A monitoring apparatus in accordance with claim 5 wherein the portable monitor is configured to be mounted on an upright ambulatory such that one of the three orthogonal directions is in a vertical direction or within a designated angle of the vertical direction.
- 35   7. A monitoring apparatus in accordance with claim 1 wherein an initiated event is communicated by the apparatus to the remote receiver by wireless communication.

8. A monitoring apparatus in accordance with claim 3 wherein:
- a first instant ambulatory performance indicia representative of movement activity in the subject is determined from the instant magnitude of the sum of the instant acceleration of the subject in one or more determined directions;
  - 5   ▪ a first acceleration threshold magnitude that is representative of a lack of normal expected subject movement is designated as a first designated performance threshold;
  - a first event representative of an absence of a normal amount of movement in the subject indicative of a possible inability to rise due to a collapse or other adverse event is initiated if the determined first instant ambulatory performance indicia is below the first designated acceleration  
10   threshold magnitude for a first designated period of time.
9. A monitoring apparatus in accordance with claim 8 wherein:
- a second instant ambulatory performance indicia representative of the instant cranio-caudal angle of the subject relative to an upright disposition of the subject, is determined from at least  
15   one of the determined instant acceleration of the subject in one or more determined directions;
  - an angle magnitude that is representative of a cranio-caudal angle of the subject relative to an upright subject where the disposition of the subject is deemed to be no longer upright is designated as a second designated performance threshold;
  - a second acceleration threshold magnitude representative of an abnormally high subject  
20   movement is designated as a third designated performance threshold; and
  - a second event representative of an abnormal acceleration of the subject followed by a laying down subject disposition indicative of a possible fall coupled with a subsequent absence of getting up from the laying down disposition indicative of a possible debilitating fall is initiated if:  
25   a) the determined first instant ambulatory performance indicia is above the second designated acceleration threshold for a second designated period of time; and  
b) within a third designated period of time of the end of the second designated period of time the determined second instant ambulatory performance indicia is greater than the designated angle threshold; and then  
30   c) the determined first instant ambulatory performance indicia is below the first designated acceleration threshold magnitude for a first designated period of time.
10. A method of monitoring an ambulatory subject including:
- a) mounting a portable monitor on the subject that includes an accelerometer to measure simultaneously the instant acceleration of the subject in at least three different directions at  
35   different instants in time;
  - b) using a processing unit in communication with the portable monitor to determine a plurality of instant ambulatory performance indicia based on the determined instant acceleration of the subject;



- c) using the processing unit to determine at least one designated performance threshold corresponding to the each ambulatory performance indicia from at least one previously determined corresponding instant ambulatory performance indicia;
  - d) using the processing unit to determine if the subject's instant ambulatory performance indicia is below or above the corresponding at least one designated performance threshold and initiating a corresponding event;
  - e) using a communications unit to communicate an initiated event to a remote receiver.
11. A method of monitoring an ambulatory subject in accordance with claim 10 wherein the at least one designated performance threshold is determined from a plurality of previously determined instant performance indicia, and the designated performance threshold responsively and cooperatively adapts to statistical changes in previously determined instant performance indicia over time.
12. A method of monitoring an ambulatory subject in accordance with claim 10 wherein the event is initiated only if the determined instant ambulatory performance indicia is below or above the determined at least one designated performance threshold for a designated period of time.
13. A method of monitoring an ambulatory subject including:
- a) mounting a portable monitor on the subject that includes an accelerometer to measure the instant acceleration of the subject in one or more determined directions;
  - b) using a processing unit in communication with the portable monitor to determine at least one instant ambulatory performance indicia of the subject from at least one determined instant acceleration of the subject in one or more instants of time;
  - c) using the processing unit to determine at least one designated performance threshold from at least one previously determined instant ambulatory performance indicia;
  - d) using the processing unit to determine if the subject's instant ambulatory performance indicia is below or above the at least one designated performance threshold and initiating a corresponding event;
  - e) using the processing unit to initiate at least one event if the determined instant ambulatory performance indicia is above or below the determined at least one designated performance threshold; and
  - f) using a communications unit to communicate an initiated event to a remote receiver.
14. A method of monitoring an ambulatory subject in accordance with claim 13 wherein the at least one designated performance threshold is determined by the processing unit from a plurality of previously determined instant performance indicia.

15. A method of monitoring an ambulatory subject in accordance with claim 13 wherein the designated performance threshold responsively and cooperatively adapts to statistical changes in previously determined instant performance indicia over time.
- 5 16. A monitoring apparatus for an ambulatory subject including:
- a portable monitor mountable on the subject that includes an accelerometer that simultaneously measures the instant acceleration of the subject in at least three different directions;
  - a processing unit that:
    - f) is in communication with the portable monitor;
    - 10 g) determines the instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions;
    - h) determines if the determined instant magnitude does not exceed a first designated acceleration threshold magnitude for a first designated period of time, where the first designated acceleration threshold magnitude is representative of a lack of normal expected subject movement;
    - 15 i) initiates an event representative of an absence of a normal amount of movement in the subject indicative of a possible inability to rise due to a collapse or other adverse event if the determined instant magnitude does not exceed the first designated acceleration threshold magnitude for at least the first designated period of time;
    - 20 j) determines the first designated acceleration threshold magnitude from a plurality of previously determined instant magnitudes; and
  - a communications unit that communicates an initiated event to a remote receiver.
17. A monitoring apparatus in accordance with claim 16 wherein:
- 25 ▪ the processing unit:
    - a) determines if the determined instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions exceeds a second designated acceleration threshold magnitude for at least a second designated period of time;
    - b) determines the second designated acceleration threshold magnitude from a plurality of previously determined instant magnitudes;
    - 30 c) determines the magnitude of the instant angle of the subject being the magnitude of the angle between the cranio-caudal axis of the subject and the cranio-caudal axis of the subject when in an upright disposition from at least one of the determined instant acceleration of the subject in one or more determined directions;
    - 35 d) determines if the determined instant angle of the monitor is greater or less than a designated angle magnitude threshold; and
    - e) initiates an event representative of an abnormally high acceleration of the subject followed by a laying down subject disposition indicative of a possible fall coupled with a subsequent

absence of getting up from the laying down disposition indicative of a possible debilitating fall if:

- I. the determined instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions exceeds the second designated acceleration threshold magnitude for at least a second designated period of time; and
  - II. within a third designated period of time after the end of the second designated period of time the determined instant angle of the subject is greater than the designated angle magnitude threshold; and
  - III. within the third designated period of time after the end second designated period of time the instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions does not exceed a third designated acceleration magnitude for at least a fourth designated period of time.
18. A monitoring apparatus in accordance with claim 16 wherein the accelerometer simultaneously determines the acceleration of the subject in three orthogonal directions.
19. A monitoring apparatus in accordance with claims 17 wherein the portable monitor is mounted on an upright subject in an orientation so that one of the three orthogonal directions is in a vertical direction or within a designated angle of the vertical direction.